

Presafe Course - Clinical evaluation report

Background	The request and requirements on clinical evaluations has increased over the years and it will not become less with the coming new Medical Device Regulation. This half day course will focus on the standards and guidance given, how to make a literature search and plan for clinical evaluation, the report and the feedback system.
Goal	To give an understanding of the process to run clinical evaluations and how to keep the evaluation up to date during the life cycle of a medical device.
Who benefits	Clinical affairs, QA/RA specialists, risk managers, marketing.
Course leader	Anette Sjögren, PREVENTIA AB Anette is a member of the Swedish (TK355 – ISO 13485, ISO 14971 and IEC 62366) and the international technical (TC210) committee and was also part of the international PMS task force.
Language	Course material is in English. Presentation in English or Swedish (depending on the participants).
Time & place	05 October 2017. Registration at 08:45 and program from 09:00 – 12:30. (Lunch from 12:30 - 13:30) Tuborg Parkvej 8, 2900 Hellerup (Copenhagen, DK).
Price	DKK 3,000 + VAT.
Course material	Powerpoint handouts and certificate of participation.

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